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Abstract

The world is becoming smaller and more competitive. The global construction market is becoming more integrated. The European Community and many other countries are turning to ISO 9000 Quality Management and Assurance Standard for the control of products and services into their markets. The European Community is in the process of developing of a single integrated market and using the development of harmonized standards and codes to implement this goal. Part of this standardization process is the development of Directives that will provide general guidance on a product/services safety, environmental capability, and personal protection. These directives are then turned over to two standard organizations that develop detailed standards. In the development of the Product Liability and Safety directives the European Community has required the use of a third party evaluation of a company quality management system based on the ISO 9000 series. The rest of the world is watching to see the success of this system.

Construction products and services fall under the requirements of both these directives and an additional one, the Construction Product Directive. All three of these directives require the use of ISO 9000. If the U.S. construction industry plans to compete in international markets they can no longer ignore ISO 9000 and must begin preparing for its use. If the U.S. construction industry continues to ignore ISO 9000, international markets will become close to our products, innovations and services. The construction industry will need to take other actions such as look at the current U.S. standards and codes systems. A national code and standards development body will need to be established to act as a representative to other countries, coordinate U.S. efforts abroad and monitor U.S. codes and standards. Single standards will need to be implemented and those designed to provide regional or local protection will need to be eliminated. A single national laboratory system for the testing and certification of products will need to be developed. The U.S. will need to increase its participation in the development of international standards. As other countries open their markets up to our products and services the U.S. will need to open our markets to those goods that meet international standards. If the U.S. construction industry plans to compete in future international markets it will need to begin to examine ISO 9000 and implement it. The construction industry has a decision to make, whether it will lead the world or be forced to follow others.

Kurt D. Blomquist

The Implications of ISO 9000 ,and the European Community on the U.S. Construction Industry

Captain USAF

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THE IMPLICATIONS OF ISO 9000
AND THE EUROPEAN COMMUNITY ON THE
U.S. CONSTRUCTION INDUSTRY

A Special Research Problem

Presented to

The Faculty of the School of Civil Engineering
Georgia Institute of Technology

by

Kurt D. Blomquist

In Partial Fulfillment
of the Requirements of the Degree of
Master of Science in Civil Engineering

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LIST OF ABBREVIATIONS AND ACRONYMS

ABET	U.S. Accreditation Board for Engineering Technology	EEA	European Economic Area
AFNCR	Association Francaise de Normalisation	EEC	European Economic Community
ANSI	American National Standards Institute	EFTA	European Free Trade Association
AQAP-1	Allied Quality Assurance Publication 1	EN	European Norm
ASQC	American Society of Quality Control	EOTA	European Organization for Technical Approval
BSI	British Standard Institute	EOTC	European Organization for Testing and Certification
CE	Communaute Europeene	EQNET	European Network for Quality System Assessment and Certification
CEN	European Committee for Standardization	ETSI	European Telecommunications Standard Institute
CENELEC	European Committee for Electrotechnical Standardization	EUAtc	European Union of Agreement
CPD	Construction Product Directive	EURATOM	European Atomic Energy Community
DIN	Deutsches Institute for Normung	FEANI	European Federation of Engineers Associations
DoD	Department of Defense	GATT	General Agreement for Tariffs and Trade
EC	European Community	IEC	International Electrotechnical Committee
ECSC	European Coal and Steel Community		

ISO	International Organization for Standards
MOU	Memorandum of Understanding
NACB	National Accreditation of Certification Bodies
NATO	North Atlantic Treaty Organization
NCEES	National Council of Examinors Engineering and Surveyors
NSPE	National Society of Professional Engineers
OECD	Organization for Economic Cooperation and Development
QMS	Quality Management System
RAB	Registrar Accreditation Board
RvC	Raad voor de Certificate
SEA	Single European Act
SEM	Single European Market
UL	Underwriters Laboratory
UNI-CEI	Ente Nazionale Italiano Unificazione

SUMMARY

Within the last several years there has been a growing interest in quality of products/services and in the acceptance of a world wide quality system standard. The standard that has been finding its way into contractual requirements for the assurance of conformance of products and services is ISO 9000 quality management and assurance series standard. The European Community (EC) through its development of the Single Economic Market (SEM) is pushing this standard into the world spot light. The U.S. construction industry needs to be aware of ISO 9000 standard series and begin preparing for its adoption. The EC represents 25% of the world construction market. Through harmonization of its standards the EC is leading the way for use of ISO 9000. Through various general and specific product directives it has made the certification of a companies quality program to ISO 9000 mandatory. The EC continues to work closely with the International Organization for Standards (ISO) and other countries on standards development. The close interface between the EC and ISO could lead to European standards and their use becoming the basis for world standards. The U.S. construction industry has displayed little to no interest in

participating in international standards development. A third party certification and registration system based on ISO 9000 has been developed by the EC and is being implemented in some format in over 30 countries. If a construction company is planning to compete it will need to start now to prepare itself for successful registration.

If the U.S. construction industry plans to compete successfully in world markets it will need to change its attitudes and focus on ISO 9000. An evaluation on current industry practices of standards development and certification of testing labs will need to be accomplished. A more harmonized system will need to be implemented. Engineers and manufacturers will need to shift their focus to the importance of quality and how it is measured and defined.

CHAPTER I

INTRODUCTION

A global market for construction products and services is becoming more and more a reality. This has been driven by the move of the European's towards a single economic market, the increased international trade in the Pacific Rim, the interest of the emerging Eastern European countries in western technology, and the growth of third world markets (Gross 1990B). Part of the globalization effort is an increased use in trade by countries of international standards. These trade agreements, along with other countries allowing increased U.S. participation in their markets are requiring the U.S. to open its markets to foreign products and services that meet these international standards. As the U.S. develops and becomes involved with international trade agreements the question of quality and acceptability of products and services becomes more of an issue. The U.S. must decide whether it will be influencing the development of international standards or reacting to them as they become the basis for acceptance of products and services. One of the main issues facing the construction industry today is the issue of quality. In the

international market the issue of, definition of, and the measurement of quality is through the use of ISO 9000 Quality Management and Quality system standard series. The use of this standard is becoming more frequent as the primary basis for acceptance of a new product or service on the global scene. The European Economic Community (EEC) has been the leading organization that has developed requirements for the use of ISO 9000 in the marketplace. The rest of the world is watching to see how successful this program will be. The U.S. construction Industry must now begin to look at the use of ISO 9000 and the other international standards if it plans to successfully compete future international markets.

Research Goals

The main objective of this research is to examine the current relationship among: ISO 9000, the EC's drive for a common economic market, how this effort is using ISO 9000, the interface between the EC use and global use, and what the implications are to the U.S. construction industry. The paper will examine the use of ISO 9000 by the EC for control of quality and acceptance of products and services. Then how that this may be translated to world markets.

To accomplish this goal this paper will be examining what the EC is and how it's market integration program uses ISO 9000; examine the development of standards, what is the ISO

and ISO 9000 Quality management series, the certification/registration issue, and the basic stages for a company preparing for ISO 9000 audit. Too, there will be a look at various issues, concerns and impacts on the U.S. construction industry. This research is the compilation and review of current literature on the identified issues. Its intended use is as a starting place to become familiar with the concepts involved with ISO 9000, reasons of why should be concerned and how a company may start its' own evaluation for use of ISO 9000.

CHAPTER II

EUROPEAN ECONOMIC COMMUNITY

To understand the importance of ISO 9000 and how it can affect the U.S. construction industry there must be an examination of the use of this standard in the development of the Single European Market. The European Economic Community and their goal of single market by 1992 is a major focal point for the use of ISO 9000 as a national standard. It is being used to control acceptance and quality of products and services in the integrated marketplace. To understand this importance there will be an examination of: what is the EEC and its importance to the U.S. and how the EC plans to develop and implement the harmonization of standards in conjunction with ISO 9000.

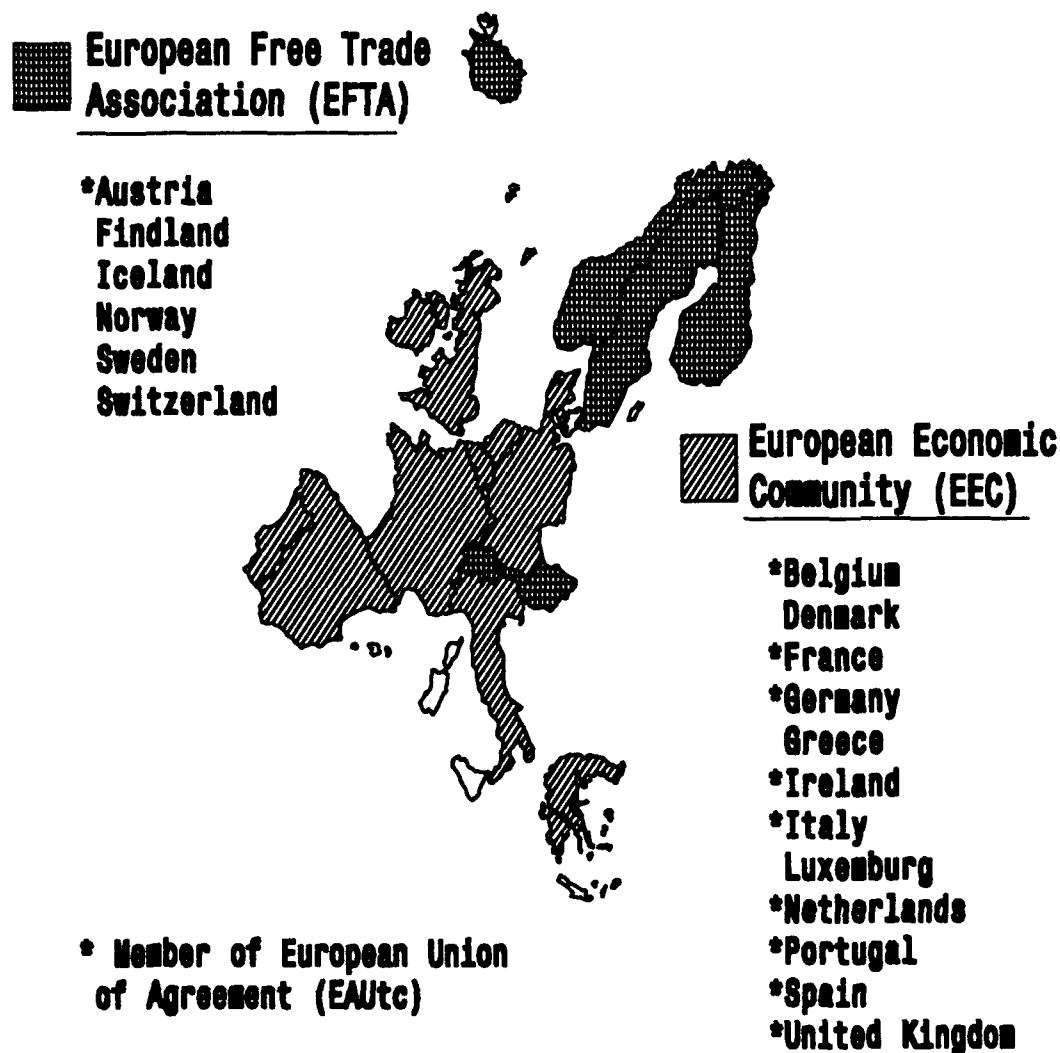
European Community

One of the most significant changes to be occurring in the international market in recent years is the drive by the EC countries to form a unified market. To accomplish the EC countries have developed a program called EC 92 which outlines their plans for this goal. The European Free Trade Association (EFTA) countries have planned to participate and unite with the EC under the umbrella of the "European

Economic Area" (EEA) (Gross 1991). This union will permit the free flow of goods and services, capital and people within the boundaries of the European continent. This will provide for the development of a third economic center in the world: the U.S., Japan, and finally the EC.

History and Development

The EC began as an organization following World War II along with the development of NATO. The EC, figure 1, consist of 12 countries; Belgium, France, Italy, Luxembourg, Netherlands, and West Germany, all of which signed the Treaty of Rome in 1957 establishing the EEC. The remaining countries joined in the following order, Denmark, Ireland and the United Kingdom in 1973, Greece in 1981, and finally Spain and Portugal in 1986 (Freund 1990B). With the joining of the last two countries it brought the EC up to a market of 325 million plus people (Freund 1990B). This is equivalent in size to the combined U.S. and Japanese markets (Freund 1990B). The goal of this organization was to create an integrated community-wide market free of restrictions on the movement of services, goods and people. The EC is composed of three communities that all member countries belong to: the European Coal and Steel Community (ECSC) which was established in Paris in 1951, the EEC established by the 1957 Treaty of Rome, and the European Atomic Community (EURATOM) setup by the EURATOM Treaty in



	<u>Population</u> (Millions)	<u>Land Area</u> (MIL SQ MI)	<u>Density</u> (per SQ MI)	<u>GNP</u> (Trillions)
EEC	324	0.9	403	\$3.3
EFTA	40	---	---	---
USA	246	3.5	68	\$4.2

Figure 1. EEC and EFTA Countries, (Breden 1990).

1957 (Freund 1990B). The term that describes these three communities working together is the EC.

The Treaty of Rome established the goal of a single market but it was not until the mid 1980's that the EC took aggressive steps towards this end. In July 1987 the EC commission passed the Single European Act (SEA). This act stated "the European Community will become an area without internal frontiers within which the free movement of goods, persons, services and capital is guaranteed." (Sawin 1991). This act brought into focus the original goals of the Treaty of Rome but more important it established a time frame in which to accomplish this goal. The SEA committed the EC to move towards establishing this single market over a period of time expiring in December 1992 (Freund 1990B). The term established to describe this process is "EC 92." The reasons for the passing of the SEA legislation were: the dedication of senior community officials to the implementation of the goals of the Treaty of Rome; leading British and Continental industrialists believed that the only way the EC could compete against the economic strength of the U.S. and Japan on the global market would be to pool resources and national leaders of the various EC countries desired an economic strategy that would guarantee economic growth and more employment within an enlarge EC market (Freund 1990B).

The expected free trade area is to be expanded when the EFTA countries of Austria, Iceland, Norway, Finland, Sweden, and Switzerland, develop mutual recognition agreements with the EC. The EFTA states began looking at this possibility in 1989 and when this occurs this will swell this market to over 360 million consumers.

Importance to the Construction Industry

Construction in Europe is a continuously growing market. In 1987 the value of construction work of the 12 EC countries totaled over \$380 billion (Krizan 1988). In 1988 U.S. design billings within the EC had climbed past \$650 million with 26 U.S. contractors capturing over \$8.8 billion worth of new construction contracts (Schirmer 1990). This \$8.8 billion represented a 71% increase in value of contracts won by U.S. companies from 1987 (Schirmer 1990). By 1990 U.S. owned firms of ENR's top 200 International design firms had obtained over 60% of the design billing in Europe with a total value of \$1.4 billion, table 1 (Reina 1991B). The total amount of billings for ENR's top 200 international design firms in Europe was \$2.34 billion, which was just over 25% of the total international market (Reina 1991B). This \$2.34 billion represented a 32.2% increase in billings from 1989 (Reina 1991B). In the European market, 56% of the consulting engineering work is performed in national markets (Schirmer 1990). The

ENR Top 200 International Design Firms
1990 European Billings

Designer <u>Nationality</u>	Amount <u>(\$000)</u>	Percent of <u>Market</u>
U.S.	1470.1	62.9
Canadian	72.3	3.1
European	772.0	33.0
British	(289.7)	(12.4)
German	(31.6)	(1.4)
French	(26.9)	(1.2)
Italian	(17.1)	(0.7)
Yugoslav	(2.5)	(0.1)
Dutch	(116.3)	(5.0)
Other	(287.9)	(12.3)
Japanese	10.4	0.4
All Others	12.3	0.5

Total 2,337.2

Total International Billings for Top 200 \$8,828.5

Table 1. 1990 European Design Billings for ENR's
Top 200 International Design Firms
(Reina 1990B).

remaining 44% of the work is exported, with 90% of that work contracted to non-EC countries (Schirmer 1990). The construction product industry also has an investment in the EC markets as shown in Table 2. The EC countries represented 16% of the world's market for construction products in 1988. This is expected to grow with the possible inclusion now of eastern european countries (Freund 1990A)

In 1990, U.S. owned construction contractors of ENR's top 250 international construction contractors, had been awarded over \$13 billion in the European market (Reina 1991A). This represented 43% of all construction contracts awarded in Europe, table 3. The European market represents 25% of the international construction contracts awarded to ENR's top 250 international contractors (Reina 1991A). Overall the European construction market is expected to continue to increase with over \$30 billion awarded in 1990 to ENR's top 250 international contractors. This \$30 billion was a 20% increase from 1989 figures (Reina 1991A). With the EC's goals of an open, market the U.S. share in both design billings and construction contracts can grow significantly.

Development of the Single European Market (SEM)

One of the first significant events in the formation of the SEM was the development of the EC White Paper in 1985 (Sawin 1991). This paper outlined the need for 279

EC Construction Market

	<u>Construction</u>		<u>Building Product Imports</u>	
	Value* (\$ Billions)	% of World Total	Total* (\$ Billions)	From U.S.* (\$ Billions)
Belgium	10.2	.50	2.067	.064
Luxembourg	0.5	-	-	-
Denmark	8.2	.40	1.256	.027
France	69.0	3.70	4.204	.084
West Germany	76.3	4.10	6.337	.178
Greece	3.7	.20	.295	.010
Ireland	2.7	.10	.456	.014
Italy	57.0	3.10	2.632	.137
Netherlands	14.9	.80	3.500	.075
Portugal	3.5	.20	.141	.001
Spain	26.0	1.40	.782	.056
U.K.	49.5	2.60	4.933	.224
Totals	321.5	17.10	26.603	.870

*Numbers for 1986

Table 2. Construction and building products for the EC
(Freund 1990A).

ENR's Top 250 International Contractors 1990
European Construction Contracts Awards

<u>Contractor Nationality</u>	<u>Amount (\$000)</u>	<u>Percent of Market</u>
U.S.	13,336.4	43.8
Canadian	87.6	0.3
European	15,206.3	49.9
French	(2,550.7)	(8.4)
British	(2,988.9)	(9.8)
Italian	(4,242.9)	(13.9)
German	(3,018.2)	(9.9)
Dutch	(1,383.3)	(4.5)
Yugoslav	(152.3)	(0.5)
Other	(870.0)	(2.9)
Japanese	1,326.3	4.4
Turkish	169.0	0.6
Others	324.4	1.1
Total	30,450.0	

Total 1990 International Awards for Top 250
\$120,1257.6

Table 3. 1990 European Construction Contracts
Awarded to ENR's Top 250 International
Contractors (Reina 1991A).

directives that would provide the road map for the creation of the SEM by December 1992 (Sawin 1991). As of early 1990 over 180 of these directives have been adopted (Sawin 1991). The SEA of 1987 restates the goals of a common market and defined a time table. It also provided another significant change that would increase the speed in which this formation could happen. The 1987 SEA also changed the requirement for an unanimous vote of the EC Council to a majority vote on legislation that involved the establishment of the single market.

One of the principle components of the development of the SEM is the development of harmonized standards and testing and certification processes. The EC in the past worked directly into their regulations specific standards and codes. In the mid 1980's, with the development of the White Paper, the EC developed a new approach to standard development. The EC Commission would develop general guidelines called directives on areas such as safety, environmental capability, liability, etc. and these would then be passed to another organization to develop specific product standards that would meet these general outlines. The EC Commission has developed 11 new directives, covering areas such as: toy safety, construction products, personal protective equipment, machinery, etc., which once adopted would become legal requirements for the sale of products or

services in the EC after 1992 (Hagigh 1992). For the construction industry the directives of primary concern will be the Product Safety, Liability and Construction Products directives.

The organizations which have been given the responsibility of developing these standards are the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELECT). The CEN has over 200 active technical committees with an average of 10 working groups per committee that are involved in the drafting standards. Both the CEN and CENELECT have agreed to use ISO standards for adoption in the EC in areas where they may exist. Since participation in both of these organizations are for EC member countries only, this restrictive participation prevents the U.S. from any direct influence on the development and use of the standards.

In the standards development there are allocated 40 committees, out of 200 or so, to building and civil engineering sector products and services (Hale 1990). The huge task of creating a SEM in construction is being approached gradually, starting from the certification and testing and product standards side (Hale 1990). At the root of the product and service certification and testing is the European harmonized standard of ISO 9000, EN 29000. The EC has also begun to approach the building regulation areas by

issuing 9 Eurocodes which provide general guidance. The area's which are covered are:

1. General Principles.
2. Concrete Structures.
3. Steel Structures.
4. Composite Steel and Concrete Structures.
5. Timber Structures.
6. Masonry Structures.
7. Foundations.
8. Structures in Seismic Zones.
9. Building Load Assumptions.

The CEN now has the responsibility to develop detailed standards based on the general codes (Gross 1991).

To ensure that these standards do truly become EC wide, in 1987 the EC adopted a new set of unified rules for the CEN/CENELECT. The crucial change of the unification rules was the requirement for the adoption of European standards by the individual member's national standard organizations/bodies (Hale 1990). The change required that any conflicting national standard had to be withdrawn and once work was begun on an European standard and no new work could be started on the national level on the same subject (Hale 1990). This philosophy was in line with the original

goals of the Treaty of Rome and is helping to push the SEM ahead. Another influence of the European's goal for a unified market and their commitment to international trade will be that EC standards will become international ones.

CHAPTER III

HARMONIZATION - STANDARDS - DIRECTIVES

An important element of the SEM unification process is the harmonization of standards and codes through out Europe. Early on they recognized the need for a single standard that could be applied to all manufacturing and service types industries for acceptance and assurance of quality. They looked to the already existing ISO standard, ISO 9000, for the system in which to develop their quality assurance program. To understand how the EC is using the ISO 9000 standard there will be an examination of the EC harmonization effort, the importance of standards and their development, and what EC Directives are and how they require the use of ISO 9000.

Harmonization

As the plans were developed for the SEM it was realized that economies of scales and the efficiencies that went with that could be used more effectively with an unified standards system. By the elimination of duplication of effort for the approval and use of a building products, manufacturers can save considerable amounts of time and money. The consumer would also benefit by having access to

new products in a more truly open fashion.

The concept of mutual acceptance of new building products actually was begun by France, Belgium, Portugal and the Netherlands in the 1960's (Breden 1990). By 1976 this coordination effort resulted in the formal establishment of the European Union of Agreement (EUAtc) whose purpose was to help the acceptance in Europe of new or improved building products not covered by existing standards (Breden 1990). The EUAtc was built around three basic principles (Breden 1990):

1. Mutual recognition of standards and information.
2. Mutual recognition of test results.
3. Mutual recognition of product certification and inspection.

Once a manufacturer received the EUAtc Agreement certification they then avoided the necessity of having to obtain approvals in each of the countries that were members (Breden 1990). By the 1980's over 100 different products: plastic windows, roofing systems, insulation glass, etc., had received EUAtc certification. Once the EC began their efforts they looked at the successful work of the EUAtc and incorporated some of its concepts into the certification system for the SEM (Breden 1990).

In May 1985 the EC Council endorsed the principles of

European standards to replace the use of individual national directives and standards (Wadsworth 1991). The EC realized that this would remove the initial barriers for open and free trade and adopted three fundamental principles that would be used to develop these standards. The principles were (Boehling 1990):

1. Regulatory directives would be developed and would not be detailed, but will contain very general essential requirements.
2. The CEN, CENELECT and the European Telecommunications Standard Institute (ETSI) would then prepare standards to meet the directives and where possible ISO or International Electrotechnical Committee (IEC) standards would be used.
3. Member countries will be obliged to acknowledge that products meeting these standards meet the essential requirements of the directives.

These principles established a new way of thinking for the use and development of standards. This approach was developed after the EC had problems with trying to harmonize 12 different standards on pressure vessels (Freund 1990A). The directives would cover "essential requirements" relating to health, safety, consumer protection and environmental concerns. The directives would provide general guidelines that a service or product will have to meet to be eligible for marketing in the SEM (Conover 1990A). They would be issued for areas when conflicts arose

or where there was a lack of EC legislation. The organization that primarily develops standards in the area of construction is the CEN. The CEN was formed in 1961 and consists of the various EC and EFTA member national standards institutions, the British Standards Institute (BSI), Association Francaise de Normalisation (AFNCR), Deutsches Institute for Normung (DIN), etc., and published its first statutes in 1976 (Freund 1990A). Along with CEN and CENELECT is the European Organization for Technical Approval (EOTA) which provides technical assessment of fitness of use and recommendations to the bodies on construction products (Hagigh 1992). Along with the development of new standards, the EC has committed to use ISO or IEC standards where they already exist. The last principle requires that if a product meets European standards and therefore meets the essential requirements, it could not be restricted from being traded within the SEM. Once a product meets these standards it will be certified and a mark of "Communaute Europeene" (CE) will be applied. This mark will provide for mutual recognition EC wide and allow free access to all markets. To go with the development of construction product standards the CEN is developing 9 Eurocodes which will be used to govern structural design issues ("U.S. Readies.." 1990).

To assess a whether a product or service has met these

standards, a European-wide quality assurance program was developed. The basis for this program is the ISO 9000 Quality Management and Quality Assurance Standard series adopted as EN 29000. This series with the other harmonized standards will turn the EC into the SEM they desire.

Standards

Having looked at how the EC is using the harmonization of standards as an element in their implementation of the SEM, a review of the use of standards and how the U.S. differs in their use from the rest of the world.

Standards are used widely as the basis for design and construction specifications and for building codes and regulations. Standards provide the vehicle for the transfer of advances in building technology from research into practices, and they are used for a frame work for product approval systems which involve testing and certification. The construction industry is heavily dependent on standards and uses them to ensure that a particular outcome is reached or that a product meet a certain performance level. Manufacturers use the testing and certification of products to these standards as a way in which to increase the marketability of their product. Consumers use standards to ensure that they receive a desire product or protect a particular interest. In a U.S. construction contract there is somewhere between 300 to 400 primary technical standards

and codes that will be referenced (Gross 1990B). It is in this use of standards and specification the construction industry controls the use of building products and services.

In the U.S., construction standards are produced in a voluntary system in which government agencies, trade associations, professional organizations, industry, producers and consumer institutions, and individuals provide inputs that are gathered and developed into a control regulation. These standards then are made available for use in mandatory building codes and contracts. Too, these standards are adopted by the 50 states plus some 50,000 local governments and each in some way enforces them differently (Conover 1990B).

There is no national organization that oversees the development or enforcement of these standards from a national level. The American National Standard Institute (ANSI) is a private organization that acts as the main coordinating body for standards produced by others. ANSI encourage the development of, and tracks the well being of the U.S. standard generating system. They also act as the main coordinating agency for U.S. activities relating to international standards participation. They represent the U.S. in the ISO and IEC. Along with no national standards' organization, there is no national testing laboratory's system that tracks and monitors laboratories. This has

resulted in a system of private laboratories that, for a fee, will test a particular product against a particular standard. Manufacturers will hire these laboratories to test their product and use this "certification" as a marketing tool for their product. Local governments and consumers cannot afford to conduct these tests and must rely on this same private system of laboratories for certification that products met the desired standard. This forces many states and local governments to check these labs to ensure that the desired standards are being used. What results is that each of these reviewing entities performs the evaluations a different way preventing little or no reciprocity of data or test results between them. This usually requires that manufacturers develop products a little differently, designers to track local standard variances, and contractors to install products differently depending on location to meet the local requirements.

In other countries standards are handled and developed at the national level with little individual involvement. There are government agencies, such as the German-DIN, British-BSI, Frances-AFNCR or the EC-CEN/CENELECT, that develop and track standards and monitor and certify testing laboratories. In the global market, businesses are looking towards the international bodies of the ISO and IEC for standard guidance. Then to third party laboratories to set

standards for testing and certification (Rennie 1991). This normally results in the more uniform application of regulations and provides to the consumer more confidence that a product meets the specified requirements since a third party is used to evaluate it. Like the EC many countries are looking to use ISO standards so that they can improve the global acceptance of their products. In the U.S., of the 89,000 U.S. standards, only 17 are directly adopted from ISO standards (Conover 1990A). The lack of use of ISO standards means that producers looking to participate in international markets must be prepared to operate separate production lines for their products going to domestic and international markets.

EC Directives

European standards are an important element in the development of the SEM. The standards are developed around the frame work of a general guidance provided by the various directives. The EC began the harmonization process by starting with the development of directives for their regulated products, figure 2. Each directive contains 6 elements that a product will have to conform to. As indicated earlier these 6 elements cover areas such as safety, health, personal protection and environmental issues. To understand the impact of directives on the construction industry will examine the Product Liability,

EC REGULATED PRODUCTS*

Aircraft and Parts
IT Equipment and Parts
Motor Vehicles, Engines and Parts
Instruments, Medical and All Other
Construction Products: Boilers and Pressure Vessels
Machinery
Materials: plastics, paper, chemicals
Electrical Machinery
Audio and Visual Tapes and Films
Telecommunications
Medicines
Others: toys, consumer goods, etc.
under development

Figure 2. EC Regulated Products ("Europe Now.." 1992)

Safety, and Construction Product directives. Explain how ISO 9000 will be used to ensure compliance of products and services to these directives.

Product Liability and Safety Directives

The EC Council has developed and adopted 11 product directives, figure 3, which range from toys to medical devices with others currently under development. These directives will become legal requirements for manufacturers once adopted by the member states. One of the first major occurrences in the development of the directives was the adoption of the Product Liability Directive in July 1985 (Wadsworth 1991). This requires that a manufacturer must maintain and present, when questioned, documented proof that their product is free from defects. This has revised the past trends of consumers having to be aware and places the burden of proof now on the producer. To provide the documentation a company will be required to have a quality management and assurance system as least as good as that prescribed by the adopted European standard, EN 29000 (ISO 9000).

The Product Safety Directive, implemented in July 1989, requires that a manufacture will have a well documented quality management system (QMS) to monitor the safety of their product throughout its foreseeable useful life (Wadsworth 1991). This QMS will be required to meet the

EC Product Directives

Transition <u>Adopted</u>	Implementation	
	<u>Date</u>	<u>Period</u>
Toys	1/1/90	None
Simple Pressure Vessels	7/1/90	7/1/92
Construction Products	6/27/91	Indefinite
Electromagnetic Compatibility	1/1/92	12/31/95
Gas Appliances	1/1/92	12/31/95
Personal Protective Equipment	7/1/92	None
Machinery	12/31/92 (nonmobile)	12/31/94
	(mobile)	12/31/96
Non-Automatic Weighing Instruments	1/1/93	1/1/03
Active Implantable Medical Devices	1/1/93	12/31/94
Type Approval of Telecommuni- cations Terminal Equipment	1/1/93	None
<u>Proposed</u>		
Medical Devices	7/1/94	6/30/97
<u>Planned</u>		

In-Vitro Diagnostics, Flammability of Furniture, Pressure Equipment, Recreational Crafts, Lifting Appliances, etc.

Figure 3. EC Product Directives Adopted, Proposed and under planning ("EC Testing.." 1991)

minimum requirements established in EN 29000 (ISO 9000).

Both these directive, and others, will require a producer to demonstrate that their product meets the identified standards by an assessment performed by a third party. The conformance to the identified requirements will be accomplished through testing and certification and by using quality assurance audits. These audits will be accomplished by a list of government authorized organizations or "bodies" who are authorized to certify conformance of a product to directive requirements. The standard that must be met for QMS is EN 29000 (ISO 9000). These directives require once a product has been certified that it meets all legal requirements a mark of "CE" will be affixed (Hagigh 1992). Once a product has this mark it must be accepted in all EC member states without further certification.

The directives that specify the use of third party assessment process requires that each member state submit to the EC a list of organizations that will be accomplishing these assessments. These organizations once submitted will become known as "notified bodies" (Breitenberg 1991). The EC will maintain a listing of all notified bodies. Then each particular government must ensure that these bodies are competent to declare a regulated product's QMS is in conformance (Breitenberg 1991). The result is that each EC country must accept the test and certification and

assessment results by these bodies from all the other member states unless there is caused not to accept. Hence once a product or service is certified that it meets all directive requirements no additional testing or certification is required.

Construction Product Directive

One of the most important piece of legislation for the construction industry was the signing and adoption of the EC Construction Product Directive (CPD). The CPD (Directive 89/106/EEC) signed in December of 1988 will take effect in July of 1991 (Gross 1991). This signified the agreement of the EC members on the requirements for building products and it required that each member state had to enact the directive into law. The directive had two basic objectives: (1) the removal of technical barriers to trade in construction products and (2) the maintenance of minimum health and safety standards (Gross 1990A). This directive applies to all products intended for permanent incorporation into buildings and civil engineering works (Gross 1990A).

As with the other directives the CPD has six "essential requirements" that must be met by a product before it can enter the EC market. Conforming to CEN or ISO standards will be the primary way in which a company will demonstrate that they are meeting the essential requirements (Gross 1990A). The essential requirements are (Freund 1990A):

1. Mechanical resistance and stability. Products or works must be designed and built such that liable loadings during construction and use will not lead to: collapse, major deformation, damage to other parts, fittings or installed equipment, or damage by an event disproportionate to the original cause.

2. Safety in case of fire. Works must be designed and built so that in case of fire the load bearing capability can be assumed for a specific period of time, spread and generation of smoke and fire is limited, spread of fire to neighboring work is limited, occupants can leave the works or be rescued by other means and safety of rescue team is considered.

3. Hygiene health and the environment. Works must be designed and built so not to pose a threat to hygiene or health of occupants or neighbors. In particular due to the giving off toxic gas, the presence of dangerous particles or gases in the air, emission of dangerous radiation, pollution or poisoning of the water or soil, faulty elimination of wastewater, smoke, solid, or liquid wastes; presence of damp in parts of the work or on surfaces within the works.

4. Safety in use. Work must be designed and built in such a way that they do not present unacceptable risks of accidents in service or in operation, such as slipping, falling, collision, burns, electrocutions or injury from explosions.

5. Protection against noise. Works must be designed and built so that noise perceived by the occupants or people nearby is kept to a level that will not threaten their health and will allow them to sleep, rest, and work in satisfactory conditions.

6. Energy economy and heat retention. Works, and the heating, cooling, and ventilation installation must be designed and built in such a way that the amount of energy required in use shall be low regarded to climatic

conditions of the location and occupants.

Many may feel that the CPD is primarily for manufacturers but designers will also be affected. Designers need to realize that since these products can satisfy the requirements of "fit for use" only when they are incorporated properly into works (Gross 1990B). Thus it will be necessary that compatibility between design, products, and construction procedures be an integrated effort so that the final product conforms to the required standards.

Combining all three directive, companies planning to compete successfully in Europe will have to look to ISO 9000. All these directives require the assessment of a producer's QMS to the minimums of EN 29000 (ISO 9000). Once a product receives the "CE" mark it will not have to meet other standards or requirements and will be able to be sold any where in the EC.

CHAPTER IV

ISO - ISO 9000 - CERTIFICATION/REGISTRATION

In the development of the Product Safety and Liability Directives the EC recognized the need for a single quality standard. This quality standard requires the ability to be able to evaluate and ensure that products and services are conforming to established requirements. The EC chose the existing ISO 9000 Quality Management and Assurance standard series to use as the basis for this certification process. Through the use by the EC this standard has had increased exposure so that other countries have now adopted it as their national standard for quality assurance. In this section an examination of the ISO and where it functions in the development of standards, the ISO 9000 standard series, how ISO 9000 series has been adopted for use, and the third party certification and registration system that has been developed by the EC will be offered.

ISO

In global markets, the recognized organization for the development and leadership in the area of international standards is the ISO and IEC. Compliance with it's standards are a strong argument for product acceptance in

international trade. The ISO was founded in 1946 to: promote the development of international standards and related activities including conformity assessment (testing, inspection, laboratory accreditation, certification, quality system assessment, and other activities intended to assure the conformity of products to a set of standards and technical specifications) and the simplifying of the exchange of goods and service world wide (Breitenberg 1991). ISO is a nongovernmental organization composed of 91 member's national standard bodies (Gross 1990B). The U.S. is represented by the ANSI with other such organizations as the BSI, DIN, AFNRC, etc. all working to develop and promote world wide standards. ISO covers all areas except those involving electrical and electronic engineering which is handled by the IEC.

The ISO operates on a one vote per country system (Conover 1990A). This is used when selecting final documentation or voting on issues with each participating country getting one vote regardless of its' size. In the past it was not unknown that blocks of countries would vote together on particular issues. ISO's work is broad and diverse with it having published over 7,000 standards (Gross 1990A). It has 166 active technical committees with subcommittees and working groups totaling 2,400 technical bodies that are working on various issues relating to product and service

standards (Gross 1990B). In the construction area there are 33 technical committees and 541 subcommittees and working groups that are producing standards primarily for construction (Gross 1990B). The U.S. through ANSI holds 3 secretariats positions: boiler and pressure Vessels, earth-moving machinery and ceramic tile, and 43 secretariat positions out of the other 541 subcommittees and working groups (Gross 1990B).

The U.S. participation has been a lack luster effort. The ISO presents a major opportunity to export U.S. standards technology and influence the development of global standards. Many nations including the EC look to the ISO for these global standards. This lack of participation has placed less than 10% of the secretariats of the construction subcommittees and working groups in U.S. leadership. Being one of the strongest economic powers in the world this threatens to slowly cripple the U.S. as new technology developed by U.S. companies will no longer be readily accepted in the world marketplace. This lack of participation is because our standards organizations are privately funded. It is very expensive and time consuming to participate in ISO activities. Usually U.S. participation is 1 to 2 persons, part timers, facing upwards of 12 full time delegates from European countries (Freund 1990A). This is because in the past the ISO has worked at a

slow rate placing a heavy financial burden on the U.S. private organizations where as many of the other organizations are subsidized by their governments (Freund 1990A). E.C. groups are government driven and sponsored where the U.S. participation is mainly industry-driven and the profit making/private sector must realize that it is to their benefit to participate in the standard development process (Dorris 1990).

ISO 9000

History

Quality has been an issue for many years both in the U.S. and the rest of the world. The ISO 9000 quality series began its life in 1959 when the U.S. Department of Defense (DoD) established a Quality Management program with the designation of MIL-Q-9858 (Sawin 1991). This was used in contracts between the DoD and many of its contractors. It was revised and enhanced four years later and has not been significantly changed since. In 1968 NATO adopted the provisions of MIL-Q-9858A in the form of Allied Quality Assurance Publication 1 (AQAP-1) (Sawin 1991). In 1970, the Ministry of Defense in UK adopted the provisions of AQAP-1 into the form of their Management Program Defense Standard (DEF/STAN 05-8) (Sawin 1991). Then in 1979 the BSI evolved the first commercial quality management system from these predecessors and it became known as BS 5750 (Sawin 1991).

The ISO assigned Technical Committee 176 to develop a quality management and assurance standard (Burr 1990). They examined and took the elements of BS 5750 and developed the ISO 9000 quality standard series which was adopted in 1987 (Sawin 1991). In that same year the British revised BS 5750 and harmonized it with ISO 9000 making both standards equivalent documents (Sawin 1992). The EC also adopted the harmonized standard as EN 29000 in 1987 (Sawin 1992). Finally in 1987 the American Society of Quality Control (ASQC) and ANSI established and published the Q-90 series documentation which was identical to ISO 9000 (Sawin 1991). Today ISO 9000 - BS 5750 - EN 29000 - Q-90 series are all equivalent documents representing the same standard.

Use of ISO 9000

Since its adoption in 1987 the ISO 9000 quality standard series is used more and more through out Europe and the world. Up until this time few U.S. companies have pursued registration under the ISO 9000 series because there were no requirements to. That is now rapidly changing. Today there is nearly unanimous world wide acceptance of the ISO 9000 series as a quality system standards which is replacing the use of MIL-Q-9858A and AQAP-1 as a contractual requirement in most two party contracts (Kallnosky 1990).

The use of ISO 9000/BS 5750 has seen significant use in contracts in the U.K.. British companies are using it as a

tool to ensure that suppliers have and are using a quality system that ensures that they have the ability to meet their product or service requirements (Burr 1990). The requirement of ISO 9000 as a regulatory agency requirement for product registration is increasing. The EC with its adoption of its Product Liability and Safety directives requiring the certification of a producer's QMS based on ISO 9000 as a requirement for marketing a product or service has increased the interest in its use. The U.S. federal government has increased its interest in using ISO 9000. The Department of Defense has issued a policy that it should be used where possible in contracts and the Food and Drug Administration has been considering replacing the current Good Manufacturing Practice regulations for medical devices with the ISO 9000 standard with appropriate modifications for their application (Breitenberg 1991).

What is ISO 9000

To understand what the ISO 9000 series is, will first describe what it is not. The ISO 9000 series does not certify a specific product. It doesn't apply to purchasing, assessment of subcontractors, or the inspection and testing of purchased components. What it does provide is a certification of the process that provides assurance that a quality management system (program) is in place and that the QMS will enable the product to meet its published quality

standards (Saunders 1991B).

The ISO 9000 series was developed originally as an advisory guide and for use in two party contractual situations. It provided a method in which a purchaser could examine their supplier's capability to provide a product and maintain it at the required specification. It allowed the supplier a way to set up and perform internal audits on their process. Today the standard is applied under much broader range of conditions and circumstances (Breitenberg 1991). The ISO set up the language within the series such that it would be relevant to all types of businesses from manufacturing (steel, electronics, etc.) to service type (medicine, Banking insurance, etc.) organizations (Kallnosky 1990). The series provides the basic guidance for selection of and frame work for a quality management system. These requirements or elements are minimums that should be examined with the user filling in the specific industry requirements (elements).

The ISO 9000 series consist of 5 standards that define a QMS, figure 4. The standard ISO 8402 is used in combination with the others because it provides for the terminology and definitions used in the series. ISO 9000 is the introduction to the series and provides the guidelines for the selection and use of the appropriate QMS model. Then

THE ISO 9000 SERIES

ISO 9000 - Quality Management and Quality Assurance Standard	Explains fundamental quality concepts; defines key elements, provides guidance on selecting, using and (if necessary) tailoring ISO 9001, 9002, and 9003.
ISO 9001 - Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing	The most comprehensive standard in the series. Covers all elements listed in ISO 9002 and 9003. Plus it address design, development and servicing capabilities.
ISO 9002 - Quality Systems - Model for Quality Assurance in Production and Installation	Address the prevention, detection, and correction of problems during production and installation.
ISO 9003 - Quality Systems - Model for Quality Assurance in Final Inspection and Test	The least comprehensive standard. Addresses requirements for the detection and control of problems during final inspection and testing.
ISO 9004 - Quality Management and Quality System Elements - Guidelines	Provides guidance for a supplier/manufacturer to use in developing and implementing a quality system and in determining the extent to which each quality system element is applicable. It examines each of the quality system elements in greater detail and can be used for internal and external auditing purposes.

Figure 4. ISO 9000 series defined (Breitenburg 1991).

ISO 9001, 9002, and 9003 describe 3 distinct QMS models with varying degree's of stringency for use in different applications. The models range from a very complex QMS model for a company that is involved in the design and development, production, installation and servicing of a product to the simple requirement of assuring quality just at the time of final inspection and testing. The final component of the series, 9004, is a guide for the application of the various elements of the QMS (Sawin 1991). Since its original publication in 1987 there has been the publication of supplements to some of the standards to cover specific areas, ISO 9000-3, Part 3 - Guidelines for the Application of ISO 9001 to the Development, Supply, and Maintenance of Software in 1991 (ISO 9000 - 3 1991) and ISO 9004-2, Part 2 - Guidelines for Services in 1991 (ISO 9004-2 1991) are two examples. The ISO 9004-2, Part 2 in its Annex A, lists specifically that one of the service organization that this can be used for is building design (Architects) activities. Additional supplements are at present being developed.

In the three QMS models there are some basic elements that are common to all. The series defines that to have an effective quality system it should have the following elements: methods to ensure that measurements are valid, that measuring and testing equipment is calibrated

regularly, the use of appropriate statistical techniques are used, having a product identification and traceability system, maintaining adequate record keeping delivery system, having an adequate inspection and testing system along with a process for dealing with nonconforming items and ensuring adequate training and experienced personnel are available. These items are minimal requirements and provide a starting point for a company. It is up to each company to expand and develop the details required for their specific product. There have been some complaints that the models do not address competitiveness elements (continual improvement, performance information, cost of the quality system, etc.) and industry/technology elements (preventive maintenance, continuing product liability, diagnostic tool control, etc.) that are important to a company operations (Kallnosky 1990). The basic goal of the standards is not to be all encompassing but a starting point for the set up of a QMS.

Adoption

The ISO 9000 series has become one of the most widely accepted models for QMS in the world. It has been adopted by most of the industrial nations as a national standard and it is the prime quality assurance standard for the EC. Even in some cases compliance with one of the ISO 9000 standard (or equivalent) is mandatory by private industry, national and regional governments (Breitenberg 1991).

The EC realized the importance of the ISO 9000 series and have adopted it as EN 29000 and are making it a requirement for product certification in their integrated market. A recent survey has shown that over 52 countries have adopted the ISO 9000 standard series as a national standard. The U.S. adopted it through the ASQC and ANSI in 1987 as Q-90 standards series and figure 5 provides a listing of countries and the equivalent standard for ISO 9000. It is expected to increase in acceptance as the EC SEM comes on line and as other countries watch the success or failure of its use. Adoption of the ISO 9000 for manufacturers and having a certified QMS will become a differentiating point between classes of suppliers (Saunders 1991B). This will be particularly important in high technological areas. A Supplier that has an approved QMS will have a competitive edge over those who do not (Saunders 1991B).

Certification and Registration

The ISO 9000 standard does not provide for a direct certification and registration system. The original intent was to provide a method by which two parties in a contract could use to monitor the quality of a product or service.

COUNTRIES ADOPTING ISO 9000 SERIES STANDARDS AS NATIONAL STANDARDS

IDENTICAL

Australia	AS 3900	Netherlands	NEN-ISO 9000
Austria	O Norm EN 29000	New Zealand	NZS 9000
Belgium	NBN-EN 29000	Norway	NS-ISO 9000
Brazil	NB 9000: 1990	Pakistan	PS: 3000
Canada	CSA Q420-87	Philippines	PNS ISO 9000
Chile	NCH-ISO 9000	Poland	ISO 9000
Colombia	ICONTEC-ISO 9000	Portugal	EM 29000
Cuba	NC-ISO 9000	Romania	RS ISO 9000
Cyprus	CYP ISO 19000	Russian-Federation	Gost 40.9001-2-3
Czecho-slovakia	CSN ISO 9000	Singapore	SS 308
Denmark	DS/ISO 9000	South Africa	SABS 0157
Finland	SFS-ISO 9000	Spain	UNE 66 900
France	NF-EN 29000	Sweden	SS-ISO 9000
Germany	DIN-ISO 9000	Switzerland	SN EN 29000
Greece	ELOT EN 29000-1	Tanzania	TZS 500
Hungary	MI 18990	Thailand	TISI ISO 9000
Iceland	IST ISO 9000	Trinidad and Tobago	TTS 1 65 400
India	IS 14000-1-2-3	Tunsia	NT 110
Ireland	IS/ISO 9000	United Kingdom	BS 5750:1987
Israel	SI 2000	USA	ANSI/ASQC Q90
Italy	UN/EN 29000	Yugoslavia	JUS-ISO 9000
Japan	JIS Z 9900	Zimbabwe	SAZ 300
Malaysia	MS-ISO 9000		

EQUIVALENT

China	GB/T 10300
Jamaica	JS 167:Part 1-2-3
Venezuela	COVENIN 3000

Figure 5. Countries Adopting ISO Standards information provided by Patricia Kopp, Administrator Standards Development, ASQC

There are three basic ways that ISO 9000 series can be used for evaluating a QMS. They are as follows (Breitenberg 1991);

1. Self-audit. This is used by the producer to monitor the major components of their quality system. It is used to increase the confidence of management in the production system. Demonstrates a commitment of the company to quality management.
2. Second party evaluation. This is the original intention of the standard. This is where the buyer usually requires and conducts an evaluation of the supplier's QMS.
3. Third party evaluation and registration. This may be a voluntary or mandatory system, which is conducted by a person or organization independent of both supplier and buyer.

The EC has made this third party registration mandatory through its Safety, Liability and individual product directive for their regulated products (Breitenberg 1991). The system established by the EC is not for an individual product certification. It is for the assessment of the quality control system that ensures a product's process or service can meet the established requirements and standards. This is what is known as certification of the QMS of an organization. The third party method has been increasing in popularity. As reported in an ISO survey, there are over 31 countries that have in existence one or more third party registration schemes.

The quality system certification/registration process starts with a request by the organization that their QMS be evaluated/audited by an authorized or knowledgeable organization in the ISO 9000 standard series. In the EC, they have established that each member state provides a list of organization(s) that would be responsible for conducting these assessments. The individual EC members are responsible for ensuring that these testing and certification organizations are qualified to conduct assessments. The member state applies for recognition of their organization in the EC system under EN 45000 series (Saunders 1991A). These organizations then become known as "notified bodies." These bodies send out what is known as assessors or quality system registrars who come into the requesting organization and perform an assessment or audit of the QMS (Breitenberg 1991). When the organization's QMS conforms to the registrar's interpretation of EN 29000/ISO 9000 standard, the registrar issues the organization a certificate of registration. Now the organization quality system is certified and their process produces products or provides services that will meet the established requirements. The "CE" mark is then applied to the product. Normally for an organization to maintain its registration a periodic audit will be conducted. After the organization QMS has been certified it is then entered into a registry

maintained by the certifying organization. This registry is open to anyone who wants to review a company and ensure that it has a QMS that conforms to established requirements. The U.K. at the moment is well ahead of most countries. They have 10,000 firms registered to ISO 9000 standard, 17 accredited third party certification bodies and 1,100 registered lead assessors (Boehling 1990).

Certification for U.S. companies

Until recently, U.S. firms wishing to become registered had to rely on QMS firms in Europe, because the notified bodies per EC requirements had to be physically located within Europe (Breitenberg 1991). Changes to EC legislation has allowed some assessing functions to be subcontracted out to companies outside the EC (Breitenberg 1991). The notified bodies still maintained the responsibility for ensuring that these organizations followed established procedures of EN 45000. The EC is working on a document, Working Document on Negotiations with Third Countries Concerning the Mutual Recognition of Conformity Assessment, that will provide guidance for the establishment of mutual recognition agreements with third countries (Breitenberg 1991).

There are a number of U.S. based organizations offering consulting services, assessment and/or QMS registration (Breitenberg 1991). Most of these companies have worked out

agreements with notified bodies in Europe. One of the companies that has been involved with U.S. firms is the BSI. In the summer of 1989 the BSI issued a letter of understanding that any registration performed by Underwriters Laboratory (UL) in the U.S. would be recognized as valid by the BSI (Burr 1990). By February 1990, UL had over 80 personnel qualified as assessors and lead assessors. Now for a fee, UL will conduct an audit of a company and if they pass the audit the company can be listed in the BSI registry as a qualified ISO 9000 supplier (Burr 1990). Thus meeting a requirement to compete in many countries in Europe. Other companies are currently negotiating similar agreements with other EC notified bodies. In 1989 to assist in lessening the confusion in the U.S. the Registrars Accreditation Board (RAB) was established as an affiliate of the ASQC. It developed a program to evaluate and accredit companies that will then register companies under ISO 9000/Q-90 standards (Burr 1990). The RAB began accepting accreditation applications for registration in July 1990. In appendix A is a list of companies providing QMS services and those that have been reviewed by the RAB are indicated. The U.S. construction industry is one of the industries most depended on certification programs for regulatory compliance and quality assurance of products. It needs to take a more active role in seeking QMS certification and gaining access

to available services.

Assessors

One of the elements of the third party certification/registration system is the use of assessors to perform the certification audit. Assessors and lead assessors are individuals who physically come in and conduct the actual audit of a organization's QMS. For an individual to become a lead assessor they must attend a registered course for lead assessors, pass an exam on procedures, and then conduct 5 third party assessments as a lead assessor within 1 year of taking the course (Burr 1990). All these assessments are closely supervised and reviewed by a participating authority such as the BSI (Burr 1990). Presently there are more than 20 registered courses which are conducted by British or European companies (Burr 1990). In April 1990 the BSI conducted a course in the U.S. in coordination with the American Association of Laboratory Accreditation (Burr 1990). Future courses in the U.S. are currently under development.

Controlling Organization

Once an organization decides to have their QMS registered and they have found an assessor organization, one of the most important considerations is that an assessor from the organization is recognized by one of the accreditation bodies.

For the EC there are 2 controlling committees for certification and registration, the CEN and CENELECT (Sawin 1991). These two committees have the final say on standards and how certification and registration happens. Currently there are over 5 accreditation bodies in operations (Sawin 1991). The National Accreditation Certification Bodies (NACB) was created in 1985 by the British government and was one of the first notified bodies (Sawin 1991). One of the first organizations that the NACB accredited for ISO 9000 certification was the Lloyds registry and later the BSI (Wadsworth 1991). Both these organizations have developed agreements with other countries for the subcontracting of assessment functions. One of the first accredited bodies to accredit assessing organizations outside their own country was the Raad voor de Certificate (RvC) of Holland. The Italians have established the Ente Nazionale Italiano Unificazione (UNI-CEI) as their accreditation body. The U.S. RAB is working to become the recognized accreditation body for the implementation in the U.S. of ISO 9000 (Stratton 1992).

Other organizations were created to assist in the coordination and mutual recognition of accreditation and certification. One of these is the European Network for Quality System Assessment and Certification (EQNET) which was formed in 1990 by 8 EC and EFTA third party

certification bodies (Wadsworth 1991). The purpose of this organization was for the development and implementation of full bilateral agreements and mutual recognition of quality system registrations and certifications among the members. The members of the EQNET are; AFAQ (France), AIB-Vinotte (Belgium), BSI-QA (UK), DQS (West Germany), DS (Denmark), KEMA (Netherlands), SIS (Sweden) and the SQS (Switzerland). EQNET will provide for the recognition of a company's QMS certification in each of the member countries (Wadsworth 1991). With similar agreements between EQNET members and U.S. companies, the agreements will provide those companies obtaining certification access to EQNET member markets without having to meet individual member states requirements.

CHAPTER V

PREPARING FOR ISO 9000 CERTIFICATION/REGISTRATION

It takes significant effort and time for a company to become certified and maintain a registered QMS. There are four basic stages that all organizations will need to pass through in getting to certification. They are: evaluation of organization preparedness, preparation of the process or service, pre-assessment and documentation review, and the final assessment review. To assist in developing a strategy for ISO 9000 certification will present these basic stages with some steps that an organization can use in their preparation.

Evaluation of Organization's Preparedness

To this point the chemical, electronic, automotive, and other major industries who are working heavily in international markets have done the most in preparing for and obtaining ISO 9000 certification/registration. They have significant experience in what it takes in obtaining this registration. It has been the experience of most that some type pre-assessment of a company's current status is required. Even though they may have an existing solid quality control program it usually require some minor

adjustments. Through experience the average length of the certification process is 15 - 18 months, without problems 6 - 9 months and if substantial work is required up wards of 24 months (Sawin 1991). One of the first steps a company must take is a self evaluation of the existing procedures, commitment to quality, etc., to determine their readiness. Management should locate and review existing quality documentation, determine what is presently being done to control quality, what does this provided information cover, and the clarity of the documentation and audit trails. Someone or a group should be appointed to review the ISO 9000 standard series and determine which of the models, 9001, 9002 or 9003, under which registration will be pursued. Once this is accomplished and the company has made the decision to commit to certification they will move next to the preparation stage.

Preparation

In preparing for the assessment there are a number of steps or areas that should be gone through to prepare the organization.

Management Commitment

One of the first steps in preparation is the commitment of the management to the up coming task. This commitment must not be just visible but an active involvement in the actual preparation and certification process. Management will need

to understand the ramifications of the certification process; the fees, changes in operation and philosophies of operations that may be required, and the discipline that will be needed to achieve and maintain certification. They must realize the extensive amount of time that will be committed to the preparation, registration and maintenance of the certification. Once the management has made their commitment and have decided this is the direction the organization should go, a cross representative committee/steering group should be appointed.

Steering Committee

The ISO 9000 series QMS models treat quality as a total organizational commitment. This requires that all involved realize that quality is the responsibility of all sections and functions in an organization. A good way to ensure that all parts of the organization are involved is to create a cross functional steering committee. This committee should be given the responsibility for the development of preparation plans and the implementation and management of the overall quality system. Since the steering committee involves all departments and sections, personnel will feel they are part of the team thus providing invaluable experience and expertise. An essential element of all the ISO 9000 QMS models is training.

Training

Training will also be an important element in your preparation for registration. It is important that all employees in the organization understand the standards and the certification objectives. They need to realize how their position affects the overall quality and goals of certification. This is made more effective when the communication is from the top down. Again this shows the commitment of the upper levels and will assist lower levels staying in focused and committed.

An initial training session should be established for the management and steering committee in the details of the ISO 9000 series. Then, a course to instruct the employees on the standards and the certification objectives, and why the organization is pursuing this effort. After accomplishing initial training, a program with procedures should be established for on going training which will include programs for new employees and for refreshing older employees to the objectives and how they affect the quality issue.

Communication

Communication within in an organization will make or break it during this process. All employees at all levels need to be kept abreast of the progress of the preparation process, the objectives, and key dates. The steering committee should be made responsible for ensuring that their

respective organizations are kept informed. An electronic bulletin board, a news letter, weekly update briefings are all good ways to get information out on the progress and status of the various components.

Development of an implementation plan

In the construction of a facility, a set of plans and specifications is required to produce the desired product. The same requirement is there in the preparation of your organization. The steering committee should develop an implementation plan of how the organization will proceed in their preparation efforts. This should include action items with suspense dates. The steering committee should have periodic meetings to review status, progress in various sections, address problems, and provide updates to senior management. The implementation plan should address the following as a minimum.

1. Review and identification of requirements.
2. Schedule of proposed plan.
3. Evaluation of adequacy of existing system.
4. Compliance or noncompliance of individual sections.
5. Listing of specific action items.
6. Assignment of responsibilities.
7. Commitments.

8. Tracking of actions.

9. System to track changes once implemented.

These should be treated as minimums and items can be added or deleted as needed. The important idea is that a plan be developed and implemented to get the organization to certification.

Development of a quality manual

One of the major philosophies that is throughout the ISO 9000 series is the emphasis on documentation. One of the most important parts of the certification process is the submittal and review by the assessing organization of the requesting company's quality manual. This manual should be developed as you prepare for the certification.

The manual should be of multi-tiered approach to documentation of your QMS (Craig 1991). The top tier should describe the ISO standards used and the organization's own quality policy. The next level should be individual department/section manuals. These manuals will define policy and detailed organizational responsibilities. They should have procedures that explain what quality task will be performed and who will perform this task. The final tier will be work instructions. The work instructions will define, in detail, how a particular task will be performed. It will also define procedures that will be used to determine if it has been done properly. This organizational

quality manual will not be a single manual but a group of manuals and instructions that provide the guidelines on how the QMS will work.

Internal Auditing procedures

Another of the important elements in the ISO 9000 QMS model and certification is the development of procedures for internal audits of the QMS. This is not only important for initial certification but for maintaining it. This system should be developed and put into place as soon as possible. This allows management the ability to continuously monitor the status and success of the establish QMS. Some areas and deficiencies that should be included in the internal audit system are (Craig 1991):

- Products/materials: inadequate identification, unapproved material, improper handling and storage, shelf life controls, etc.
- People: inadequate training, lack of awareness of requirements, non-compliance with existing procedures, etc.
- Corrective actions: corrective actions not determined or documented, corrective actions slow or not fully implemented, etc.
- Documentation: unapproved documents, procedures do not match practices, unofficial changes, obsolete documents in use, etc.
- Suppliers: No approved or incomplete suppliers list, inadequate communication of requirements to supplier, etc.
- Processes: new processes not qualified,

calibration incomplete, etc.

Corrective Action System

A corrective action system is important to certification, but it is also critical to the quality system so it can be continually maintained and improved. This system should be established when the internal auditing procedures are developed. Procedures should be established to determine the root causes of problems and track the correction effort. It should document commitments and time tables that corrective actions will occur in. Finally it must be able to verify that the corrective actions have been taken and the effectiveness of the actions.

Pre-assessment and Documentation Review

To adequately evaluate the established QMS, an assessment to the proposed standard should be accomplished. The organization should bring in a third party from outside of the organization to perform a preliminary assessment. This will give opportunity to identify deficiencies, problems or other issues with the established QMS before attempting the final assessment. In most cases the QMS is not totally prepared, and this is why an initial evaluation is so critical. Now the organization can go in and correct the deficiencies, rework manuals, and train personnel. Once corrective actions are completed the organization is ready

for the final stage.

Assessment review

The organization has selected who will do their assessment, and has also determined that the certification received will be accepted by their desired accreditation body. The first step is to submit a copy of the QMS manuals to the assessing organization for review. They will then schedule your audit and come to your organization to perform it. You will be provided a list of minor discrepancies which you can correct. The assessors will return and determine corrective actions have been taken and then certify your QMS meets the desired ISO 9000 standard.

Your organization is now certified. This is not the end though, since continuous tracking and evaluation must continue to maintain and improve the QMS. Many of the certification/registration organizations require that an organization be recertified every three years or so (Sawin 1991). In appendix B is a case study of a company who successfully became certified in 1991. It shows how the Du Pont Imaging System Plant in Towanda PA successfully was assessed by the BSI through UL according to the requirements of ISO 9002.

CHAPTER VI

IMPLICATION - CONCERNS - IMPACTS

Implications

Development of a QMS

The EC recognized the importance of the ISO 9000 series and has used it as one of their key elements in the development of their EC "92" program (Von Nuland 1990). As a result of the inclusion of this standard in their policy, the EC will have the potential to influence how product standards are used and the requirement for demonstration of conformance in the world market. This adoption was accomplished through the EC commission requiring the CEN to develop a European harmonized standard to ISO 9000. With minor changes ISO 9000 was issued out as EN 29000 series. This series is the prime quality control standard that is referenced in contracts between parties. As a result, the 12 member nations of the EC and 6 members of the EFTA must adopt this standard as their national standard (Boehling 1990). This resulted in more and more European businesses using the ISO 9000 series to document, implement, and demonstrate their quality assurance system. One of the

major requirements, will occur when a manufacturer or business wants to provide a product or service in Europe and 'other international markets, they will be required to develop a quality system based on ISO 9000 (EN 29000).

Shifting of Responsibilities

As discussed earlier, the EC has developed and adopted several legislative acts and directives that cover what they refer to as "regulated products." The two basic product directives: the 1985 Product Liability Directive and the 1989 Product Safety Directive, require the use of EN 29000 (ISO 9000) as the main standard to show that the service or product has a certified quality system. The Product Liability Directive requires that a documented and well implemented (ISO 9000) quality assurance system be in place to demonstrate that a product is free of defects and meets the guidelines of the directive (Boehling 1990). This directive shifts the burden of proof that a product or service is free from defects to the manufacture/producer. The 1989 Product Safety Directive requires that a manufacturer and importer will have to maintain and have available a more complex data base that will be able to track the safety of a product through its foreseeable life time. This will require dramatic changes in the manner in which manufactures track and market their products. They will have to build data bases on characteristics,

performance, etc., and have it available for customers. Designers will have to become more aware of life cycle analysis on the products they specified an use in their designs.

Rise in use of ISO 9000

A global implication is that the EC's drive for a single market is leading an increase in use of the ISO 9000 series through out the world. The Europeans are providing assistance to developing nations and others with the uses of new technologies and in the development of standards in their individual countries (Conover 1990A). Of course the Europeans are pushing for the adoption of "European Standards." A good example is Saudi Arabia; where they initiated a standards development program and the EC provided technical assistance in the development of standards and certification process. Now many of the Saudi Arabia standards look very much like European ones (Conover 1990A). Along with the assistance they provide to other countries the EC through the CEN have signed an agreement with the ISO to increase technical cooperation between the two organizations. The Vienna Agreement signed in June 1991 provides for the development of several procedures that will improve performance and increase the cooperation between the two organizations. The improvements included the reporting of work activities and sharing of draft standards between

the two (Hagigh 1992). The goal of this is to speed up the development and adoption of standards in both bodies and to avoid duplication of work (Hagigh 1992). The IEC and CENELECT have also signed similar agreements. This effort has created a global push for the use of ISO 9000 and now over 52 countries have adopted this series as a national quality standard.

The implication for the U.S. construction industry is that it needs to begin looking at the implementation of ISO 9000 series. One of the results of the European's single code approach is that Europe may become a global highway for new and innovative technologies. As many other nations follow suite, it is questionable how long our customers will accept

our present patch work of standards and testing procedures. The undercurrent of universal acceptance of the ISO 9000 series is there: the Ministry of Defense in the UK and NATO have adopted the standard, the U.S. Department of Defense has issued a policy statement towards adoption; as have Mexico, Canada and Japan and the U.S. Medical Products Device Industry is moving towards adoption of ISO 9001 as a replacement to the current Good Manufacturing Practice Standards (Sawin 1991). The final implication of all these changes is that the construction industry may become restricted to just the U.S. markets and lose its global

competitiveness.

Concerns

There have been several areas identified as areas of concern for the U.S. construction industry in relation to the EC and ISO 9000 (Schirmer 1990). The areas identified are: product reciprocity, professional licensing, and the development of standards and codes.

Reciprocity

At present, the EC has proposed that reciprocity of EC goods and services will be required before a non-EC country will be granted rights in the single market. This is aimed primarily at goods and services currently not covered by international trading rules such as the General Agreement for Tariffs and Trade (GATT), which the U.S. is a participating member of, and the Organization for Economic Cooperation and Development (OECD) (Schirmer 1990). The EC general view is that it cannot grant increased access to its own market without ensuring that it will have adequate access to other foreign markets. The concern for the construction industry is that if reciprocity agreements are not available this could lead to the exclusion of new building and product technology developed in the U.S., thus preventing those firms working in EC from using it in design. This can be accomplished by using the requirement for mutual recognition before access to markets is granted.

The other concern associated with this is reciprocity would open up our markets to both EC engineering firms and products thus increasing competition. There would be no way to prevent a company from competing here if they meet the established international standard.

Licensing

As within the U.S. the issue of licensing of engineers and its reciprocity is a concern. Many states and countries use licensing as a way to provide assurance that the public interest can be protected. Presently in the EC a non EC engineer needs to qualify for a license in each of the member state that they would want to practice in. This is similar to the current licensing system in the U.S.. There is an EC directive that will allow an engineer to practice in another member state as long as they can satisfy the entry requirements. What makes this effective is that it does not allow member states to set requirements that more restrictive then prescribed in the directive. This will allow an engineer to practice EC wide once they meet one of the EC member states requirements.

Presently National Society of Professional Engineers (NSPE), the National Council of Examiners, Engineers and Surveyors (NCEES) and Accreditation Board for Engineering Technology (ABET) are working with the European Federation of Engineer Associations (FEANI) in the establishment of

reciprocal equivalency in academics, examination, and work experience (Schirmer 1990). At the moment two agreements are in the process of being reviewed and confirmed by the participating countries. The basic outcome of these agreements will be that U.S. engineers will be academically acceptable in Europe if they meet these two basic requirements: (1) a degree from an ABET accredited engineering program, and (2) the passing of the NCEE's Fundamental exam (Schirmer 1990). Combined with these agreements and others on experience and ethics, a U.S. engineer completing these requirements for registration in one FEANI country will be able then to practice in any of the other twenty (which includes the EC countries) FEANI countries. European engineers will be able to be registered in the U.S. if they meet similar requirements, have a valid engineering degree and pass the two NCEE's examinations (the Fundamental and the Principles and Practices exam) (Schirmer 1990).

Standards and Certification

The major concern in the standard and product certification issue is their development. The European standards development process is not open to U.S. or foreign participation. The main organization, the CEN, is developing a system of unified standards and codes for implementation EC wide. Since there is little chance for

U.S. participation, there is a significant possibility that the standards adopted will not recognize U.S. construction technology. As a result of this non-recognition, the U.S. may be forced in some way to change their design and manufacturing practices to stay competitive (Conover 1990B). In the development of standards CEN has agreed to ISO standards where they exist. This is leaving many firms confused and not sure what standards or codes should be used. The close ties between the EC and ISO is allowing the EC to have a dominating influence on world standards. This creates the possibility that the rest of the world may end up using European codes as a basis for their standard system. Leaving the U.S. in a significantly less competitive position.

Impacts

One of the first things that may be seen is that the acceptance of building products in the EC will be based on the conformance to the CEN or ISO standards. One of the ways to avoid this would require that the manufacturer prove that the standards the product was produced to meets the CEN standard. Another method would require the development of a mutual recognition system. Manufacturers will have to seek ISO 9000 certification/registration or they will have to prove that they meet the requirements in each country they wish to sell in. These requirements can be taken a step

further to the global market as other countries adopt the quality assurance system used by the EC. This will require manufacturers to prepare themselves for certification and registration to ISO 9000 standards if they plan to compete outside the U.S. A side affect of mutual recognition will be increased competition from European and other countries since their products can no longer be restricted from our markets.

Since the U.S. has had limited or no participation in the development of ISO standards, the risk is run that high tech and low price U.S. construction products will not be covered by the new standards, causing them not to be able to compete effectively in Europe or in other world markets. To be able to compete the U.S. manufacturers will be forced to offer similar European product certification and assurances that their products will perform satisfactory (Breden 1990). This will push U.S. manufacturers to provide similar warranties that are provided by Europeans. To be able to receive the proper certification and registration of products U.S. manufacturers will have to revise the way they develop and track their products. They will have to maintain and have available data base information for their customers on their product's expected performance characteristics, life cycle cost, durability, capability to meet environmental and safety considerations. This will

then be coupled with field installation instructions to meet the expectation and requirements of their customers. This information is also a critical element of the required quality assurance certification documentation. No longer will minimum test data and simple descriptions be acceptable to market an item in Europe and eventually the world.

Both engineers and manufacturers will have to change their thinking on how facilities and the items that go into them are designed and produced. There is significant difference in thought between Europe and the U.S. on quality. The Europeans have always stressed high performance and durability in their designs and products where the U.S. has focused more on cost/performance of the desired product. This has resulted in European designs and products being viewed as over designed and expensive (Breden 1990). This emphasis is because for years Europeans have experienced housing shortages that have resulted in multiple generations living in the same house (Breden 1990). The focus then is more to the long-term durability of a product or service. Assurance of durability is built into the certification process through the demonstration of a company to provide a product or service consistently to a specified level. This will force U.S. manufacturers to meet similar certification process as so that their products can compete successfully.

As European standards become the "bench mark" for ISO

standards, European manufacturers will produce higher and higher levels of performing building products to meet the European marketplace (Breden 1990). It is expected that these products will then be able to meet any standard or certification requirements developed in the world. This would result in the establishing of European standards as "defacto world standards" and the certification procedures they develop as "world certification procedures." If a company plans to compete outside the U.S. they will have to meet these standards.

Another area that will be greatly affected will be the methods by which building products are tested and certified in this country. As a result of the SEM, the dependence on the ISO 9000 series and the procedures built around that standard series, U.S. manufactures may find that their test data may no longer be acceptable or valid. This will force companies wishing to compete to conduct European tests and certifications processed by an EC recognized body (Conover 1990B). If the U.S. manufacturers do not wish to have European laboratories conduct product certification, then the manner in which the U.S. laboratory system operation will need to be changed. The U.S. will have to change it's voluntary testing and certification process into a coordinated mandatory and national program. Manufacturers, private and governmental testing laboratories will no longer

be able to act independently. They will have to be accredited by some type of nationally recognized body. This body will have to be developed between private industry and the government. Mutual recognition and acceptance to the same standards used by the EC (ISO 9000) and other countries will have to be coordinated to ensure equal footing and world wide acceptance. Then all the laboratories will have to be accredited, registered, and monitored by this national body to ensure that the standards are met.

With mutual recognition between the U.S. and the rest of the world, restructuring will be required of the building standards, codes and regulation systems. The existence of over 800 voluntary standards and codes will have to be revised. No longer would local governments be able to use these codes to protect local interest. A national system of standards would have to be implemented with local codes being no more restrictive than the national codes. If not, then EC and other countries would be required to negotiate 50 separate mutual recognition agreements. The U.S. construction industry should support the creation of a single national organization that would be the focal point for the development and implementation of these codes and standards.

Consulting engineering would become more competitive as mutual recognition and acceptance of qualifications become

more wide spread. No longer will firms have to work through local partners and the concept of a global engineer will become the norm. As the EC develops legislation which will allow an engineer who qualifies in one member country to practice in any of the other member countries, and the ISO and other countries adopt the same procedures, an engineer will be able to work in the U.S. and design a facility in Germany. This would increase the competitiveness of U.S. engineers but it would also open our markets to foreign firms increasing competition at home.

How engineers are taught would have to be revisited. No longer would it be acceptable to instruct only on U.S. design procedures, global techniques will have to be introduced. Metrics and their use would become more of an issue. The U.S. is one of the few remaining countries that still work in the British units of in-lbs. We would have to move to the metrics or maintain two separate production/design processes since soft conversions will no longer be accepted.

CHAPTER VII

U.S. ACTIONS

The EC has chosen to use the ISO 9000 series as the main way of ensuring a product or service meets established requirements. As the EC gains in strength, conformance of products and services to CEN or ISO standards will become critical. This will force U.S. companies to demonstrate that their products meet the essential requirements of CEN/ISO standards. These same EC standards will become increasingly more influential in the global market as the EC and CEN works closely with the ISO and other countries in the development of standards. The U.S. must develop some type of response or action plan if it plans to compete in the global markets of the future.

Increased Participation

If the U.S. is to compete in the international market we must increase our participation in the standard setting procedures and organizations. Since the U.S. cannot have direct representation on the CEN and CENELECT we must work through the ISO. As described earlier there has been limited U.S. participation in the ISO which has mostly been noneffective. The issue in the future will be whether the

U.S. plays a strong influence on the development of international standards which are rapidly becoming the basis for the acceptance of products and services world wide. Will the U.S. become a follower and have to catch up to the rest of the major economic powers? Participation is critical to the construction industry since it is heavily dependent on standards and testing and certification of its products. The U.S. must take a more active role if it plans to strengthen its position in the international marketplace and broaden the receptivity of U.S. technology, construction products and professional services.

The U.S. must become more involved in the ISO and exert leadership in the numerous ISO committees relating to construction products and design. Where U.S. standards are superior to others the case must be taken to the ISO to revise or develop standards according. Both the government and private industry must take an active support role with ANSI in this participation effort. Specific targets and goals need to be established and commitments made to place U.S. technology and construction practices in the international standards of the ISO. Private industry needs to closely track and follow the happenings on the international scene. The construction industry must pull together and be willing to fund support or be prepared to lose out.

National Harmonization Effort

The U.S. construction industry needs to harmonize its own standard and accreditation and certification system. A national recognized certification and testing system needs to be established which can work effectively with the ISO and other countries. This will assist in the development of mutual recognition of product and service criteria for both domestically sold products and those programmed for the international market. States and local governments must work together to establish programs and procedures whereby they can agree on what requirements testing and certification agencies must meet. Based on this uniform testing and certification, the results can be mutually recognized, along with this states and manufacturers need to communicate with each other on the latest issues and occurrences in the international market to determine what kind of responses are required. States and local governments need to make the effort to use and enforce the latest editions of standards. They should uniformly rely on one program for acceptance of new and innovative technologies. The U.S. cannot survive and compete effectively on the current fragmented and biased standard and code enforcement system we have.

Engineering curriculums should be revised at all major engineering institutions. Courses should now include

information on the various ISO design standards along with U.S. design procedures. There should be a complete conversion to the use of the SI system in design and instruction of. This would include moving more rapidly at the primary grade level of the instruction of metrics. Engineering students will have to become more proficient in these skills to increase our competitiveness on the international scene.

CHAPTER VIII

REVIEW, CONCLUSION AND RECOMMENDATIONS

Review

The construction industry, like many of the other industries is rapidly moving towards a global market. No longer can a company just focus on the domestic market and not be affected by what is happening in the international scene. The issue of product quality and acceptance has been increasing in interest in the last several years. In international markets there has been a strong under current for the world wide acceptance and use of the ISO 9000 Quality Management and Quality Assurance Standard series as a universal quality standard. Conformance to this standard has become a requirement in contracts in many of the industrial countries. This standard has been adopted in the U.S. by ANSI in the form of the Q-90 series. The U.S. construction industry is very heavily depended on standards and certifications of its services and products. It can no longer ignore the changes that are occurring on the international scene. If companies plan to compete in those markets they will have to conform to the use of this standard series. As customers watch and see the benefits

that are occurring by using ISO 9000 they will begin to demand its use here.

To understand the implications to the U.S. construction industry, this paper examined the relationships among the ISO 9000 series, the EC's drive for an unified market, how this drive used the ISO 9000 series and the interface between European and global standards. This was accomplished by looking at the development of the EC and its goal of a SEM by 1992. With the EFTA countries looking to join the EC, this joining would bring this single market to 18 countries with over 340 million consumers and contain over 25% of the world's construction market. To accomplish this goal the EC passed many legislative acts and developed a listing of over 200 directives that once implemented would create this single market. They then required that each member country would then have to enact these directives into law as they were adopted by the EC. This insured EC wide acceptance. One of the important elements that was identified for the development of the SEM was the need for European wide standards.

To start the process the EC decided that they would begin with what they classified as regulated products. The initial attempt at harmonizing 12 standards for pressure vessels was very difficult and time consuming. The EC determined it needed another way to approach this task, so

they developed a system where the EC Council would develop general guidance called directives on various issues. These directives would contain 6 essential requirements that a product or service had to meet to qualify for access to the SEM. The essential requirements covered basic areas of safety, health, personal protection and environmental issues. These directives were then passed down to two organizations, the CEN and CENELECT, who would then develop detail standards.

The CEN and CENELECT were composed of the national standards organizations of the member countries. These organizations would then develop standards that would then be adopted EC-wide. To reduce duplication and increase the speed of development the CEN and CENELECT have agreed to use and adopt ISO standards where they exist. So the ISO standards would become national standards for the various EC member states. One of the first critical areas the CEN and CENELECT recognized was the need for a solid quality assurance standard. They recognized the desired qualities in the ISO 9000 series and adopted it as EN 29000. Using the ISO 9000 series they developed a third party certification and registration system for products and services. This required that each country provide a listing of organizations that would track and ensure that companies had and maintained a quality assurance program. They were

to ensure that these programs met the requirements of the various directives. These bodies became known as notified bodies. These bodies then certified other organizations to perform various functions of the certification and registration process. These organizations became known as assessors or registrars. This provided a standard testing and certification process such that if a product or service was certified by one of these organizations it was recognized by all.

There are three directives that greatly affects the U.S. construction industry. The Product Safety, Liability and Construction Product directives all require the use of ISO 9000/EN 29000 series to show conformance to the requirements of the directives. The Product Liability Directive requires that a producer has a well documented QMS that demonstrates their product or service is free from defects. This information has to be made available if requested by the consumer. It also maintains that an organization, if they receive components, is required to ensure that their subcontractors meet these requirements. This has placed the burden of proof of no defects on the producer. The Safety Directive requires that a producer maintains documentation of a product's safety through its foreseeable lifetime. To accomplish these requirements the EC has required the use of the ISO 9000 series.

With the decision of the EC to use ISO standards whenever possible and the development of a close working relationship there exists the possibility that European standards may become global standards. The U.S. does not have direct input into the CEN and CENELECT activities. The area that they can provide input is through the ISO. The ISO is the main organization that promotes and develops standards for use in international trade. Each of the 91 member countries are represented by their national standard organization. For the U.S. this is ANSI. The U.S. participation has been limited and mostly non effective. There is less than 10% of the 541 various construction related working groups and subcommittees that have U.S. leadership. What this means is that U.S. standards, technology, and innovations are not being championed and may be left out of future standards. The lack of participation is primarily do to that most countries provide governmental support to their representative organization. The U.S. representatives are privately funded and it is expensive to participate in ISO activities. Along with the close relationship of the CEN and the ISO, the EC actively promotes its standards and certification process. It will provide assistance to any country that requests it for the development of standards and product certification and registration systems. This has resulted in many countries outside of the EC have

standards and certification systems that are very similar to theirs. This increased interest in international standards has lead to the adoption of the ISO 9000 series as the national standard in over 52 nations. The use of a third party certification system has been identified in over 31 nations.

The ISO 9000 standard is 5 manuals that provide information on the minimum elements that a quality management system should have. The series does not certify a product but certifies the quality system that ensures that a product or service will meet established requirements. The series outlines three models that can be used depending on the type of process that your organization uses. They cover a process that is involved with the assurance of quality through design, development, production, installation and servicing to quality assurance required at final inspection and testing.

The series is being used in a third party certification process. If a company desires to have their QMS certified it will take anywhere from 6 to 24 months depending on the status of existing quality system. The certification process uses an assessing organization to come in and conduct an audit to the desired ISO 9000 standard model. Before this assessment, most companies need to prepare. They will typically proceed through four basic stages in

their preparation. The organization will have to perform an initial self evaluation of preparedness, the preparation of the process, a pre-assessment and documentation review, and finally the actual audit. Once an organization has successfully been certified their company can be registered as having a certified QMS. This registry is then available for consumers to review.

Conclusion

From this examination it has been determined that the use of ISO 9000 will have an impact on the U.S. construction industry. The U.S. construction industry can no longer ignore ISO 9000 with its implications and benefits. Benefits will be seen in that qualification as a certified ISO 9000 supplier or service organization will open up access not just to the EC marketplace but to many other international markets. This will occur with lower cost and time since the world wide acceptance is there for the standard. No longer will a manufacturer or engineering firm have to seek qualifications in each country in which they wish to participate. With the use of ISO 9000 there will also be an increased consumer confidence in their product. Internally the ISO 9000 series provides a vehicle with which to improve quality and productivity by monitoring the process. By examining the product's process companies will be able to achieve higher levels of quality and productivity

using the non-biased independent professional assessments. Many of the elements that are addressed in the ISO 9000 series are the fundamental building blocks for good management. It will also provide increased confidence of management in their product and process.

To start receiving these benefits the construction industry will need to change some of its operating philosophies. Construction product manufacturers and engineers will have to focus more on the characteristics of a product and how it interacts as a whole in a completed work. Manufacturers will have to start maintaining larger data bases by tracking and evaluating the characteristics of their products for its foreseeable life. These data bases will have to be made available upon a customers' request. This will require continual feed back and manufacturers accepting responsibility for a product and ensuring that it is used correctly. The way projects are designed will have to be examined. Designers will have to work with contractors to ensure that the designs and methods that will be used to construct the works will meet all specified requirements. Contractors will have to monitor and ensure that subcontractors are certified and meet the established requirements.

To ensure that U.S. building technology and products do not become shut-out from world markets the U.S. construction

industry will need to participate more actively in the ISO. Both private industry and the government need to improve their support for participation in the ISO and its standards development program. Professional societies, industry groups, local governments, etc., all need to join into a national organization to track and keep up on the occurrence in the international scene.

Another area that will need to be examined and streamlined is the current U.S. building standards and product certification system. If the U.S. presses for mutual recognition in world markets many countries will be requesting, and have stated, they want the same considerations in our markets. Presently there is not a single point of contact or single entity that controls the issues relating to standards and product certification. Each state and local government use and enforces the existing standards and codes differently. Of the 89,000 plus standards in the U.S. only 17 relate to ISO standards. Manufacturers, state and local governments all use the current system of private laboratories. There are no standards that these laboratories must meet so there is no reciprocity between states, local governments or other enforcement agencies. This would then require that 50 plus mutual agreements be developed. To avoid this, a national organization will need to be developed that would oversee

standards development and maintain control and certification over testing laboratories. The single point for standards development would ensure that conflicting or biased standards were not used. They would be the focal point for all international interfaces and issues. A single laboratory certification and testing system would assist in reducing cost to both consumers and manufacturers. Instead of having a product tested by several laboratories to meet the requirements of different areas, a single test could be conducted and the results accepted by all. States and local governments would be able to combine efforts and reducing cost by having reciprocity in test results. This independent agency would provide a watch dog over laboratories and give the consumer increased confidence in the results.

With the reciprocity of products will come the reciprocity of professional licensing. This would allow an engineer to become licensed as a global engineer. Once meeting the established requirements in one country all others that prescribe to the international standard would accept the competence of the professional. This would allow consulting firms to seek work world wide and reduce the requirement for local partners and joint ventures. To be able to receive this global registration, universities will have to change their curriculum. They will need to begin teaching more in

metric units and provide familiarization with international standards. On the negative the reciprocity and open markets will increase the competition in the U.S. market by foreign firms.

The U.S. construction industry has a decision to be made within the next several years. The construction marketplace is becoming an international one and if a company plans to be competitive they must make the decision to begin working to certification of their QMS to ISO 9000. Without this they will be at a great disadvantage. The construction industry must make a commitment to increased participation in the international community. With out this participation U.S. building products and technology will be at a disadvantage. European standards will become the norm and U.S. manufacturers will be forced to meet them with no input. How long will U.S. consumers sit back and watch as new technologies are being used by others before they demand them. The industry will have to decide whether it wants to become a dual tracked industry with a company deciding whether they will compete in international markets and therefore set up their structure accordingly or compete in domestic markets only. If they wish to compete in both they will be required to maintain a more expensive dual organizational structure. The use of ISO 9000 and other international standards is increasing. The world is

changing and becoming smaller and more integrated. The emergence of the EC single economy, increased activity in the Far East and emerging eastern bloc countries are all driving the world economics towards unified markets. The U.S. construction industry will have to decide whether it will lead in this effort or be left behind.

Recommendations for Future Work

At the start of this paper the author stated that this was a starting point for the evaluation of the implication of the ISO 9000 series. To demonstrate the importance of this standard there has to be an examination of how it is being used and what this usage means. This provides ample areas that can be investigate in much more depth. One of the first areas is the EC and their harmonization effort. They are well under way but the full impacts have yet to be realized. The success or failure of single codes and standards in the EC is a good study for a successful program to nationalize our fifty states various programs.

The actual use of ISO 9000 is another area for studying. As described, the standard can be used in various methods, self-audits, two party evaluation, and third party evaluation. It would be of interest to determine which method is being used most often and the success or failure of each. The expansion of the ISO 9000 to cover other elements that are not addressed is another area of study.

As mentioned, some feel that the standards lack other important elements like competitiveness (i.e. continuous improvement, performance information, customer satisfaction, etc.) and industry/technology (i.e. work station management, diagnostic tool control, preventive maintenance, etc.). It would provide an opportunity for someone to look at how these types of items could be developed into the QMS models. Another area could be the development of how a consulting engineering firm, a contractor, or building product manufacturer would go about registration.

Another area that was not discuss, but is an integral part of future competitiveness, is the issue of metrics use. It would be of interest to look at the impacts to convert over to the use of metrics in all facets of the construction industry.

The final area would be a closer examination of the implications of the lack of participation of the U.S. in the ISO and examine what would happen if other countries' standards became the bench mark for international trade.

APPENDICES

APPENDIX A - QUALITY SYSTEM REGISTRARS

The following represents an "un-official" listing of registrars currently based in the U.S. and Canada. List provided by Patricia A. Kopp, Administrator Standard Development, ASQC, 611 East Wisconsin Avenue, PO Box 3005, Milwaukee, WI 53201-3005.

ABS Quality Evaluations, Inc.*
Robert C. Sutton Pres.
263 North Belt East
Houston TX 77060
Telephone: 713-873-9400

American Gas Association
Laboratories (AGA)
Stephen Gazy
8501 E. Pleasant Valley Rd.
Cleveland, OH 44131
Telephone: 216-524-4990
Ext. 8349

AT&T's Quality Registrar*
John Malinauskas
650 Liberty Ave.
Union, NJ 07083
Telephone: 908-851-3058

Bureau Veritas Quality
International (NA) Inc.*
Greg Swan
509 North Main Street
Jamestown, NY 14701
Telephone: 716-484-9002

Canadian General Standards
Board
James Littlejohn
9C1 Phase 3
Place du Portage
11 Laurier St.
Hull, Quebec
(Mail) Qualification and
Certification Listing Branch
Canadian General Standards
Board

Ottawa, Canada K1A 1G6
Telephone: 613-956-0439

Det norske Veritas (DnV)
Industry, Inc.
Yehuda Dror
16340 Park Ten, Place, Suite
100
Houston TX 77084
Telephone: 713-579-9003

Intertek Services Corporation
Don R. Swanner
9900 Main Street, Suite 500
Fairfax, VI 22031-3969
Telephone: 703-ISO-9000

NSF International
Ted Anderson
P.O. Box 130140
Ann Arbor, MI 48113-0140
Telephone: 313-769-5197

Quality Management Institute
Malcolm J. Phipps
Suite 800 Mississauga
Executive Centre
Two Robert Speck Parkway
Mississauga, Ontario Canada
L4Z 1H8
Telephone 416-272-3920

Quality Systems Registrars,
Inc.*
Scott Kleckner
1555 Naperville/Wheaton Road,
Suite 206
Naperville, IL 60563
Telephone: 708-778-0120

SGS Yarsley Quality Assured
Firms
John Brookes
1415 Park Ave.
Hoboken, NJ 07030
Telephone: 201-792-2400

TUV America, Inc.
Manfred A. Popp
5 Cherry Hill Dr.
Danvers, MA 01923
Telephone: 508-777-7999

TUV Rheinland of North America,
Inc.
Joseph DeCarlo
12 Commerce Rd.
Newton, CT 06470
Telephone: 203-426-0888

Underwriters Laboratories, Inc.
Charles Mauro
1285 Walt Whitman Rd.
Melville, NY 11747
Telephone: 516-271-6200

Underwriters Laboratories, Inc.
Peter Chresanthakes/Jeff
Dohrmann
333 Pfingsten Rd.
Northbrook, IL 60062
Telephone: 708-272-8800

Underwriters Laboratories, Inc.
Stuart Walker/Steve Schmid
12 Laboratory Dr.
Research Triangle Park, NC
27709
Telephone: 919-549-1400

Underwriters Laboratories,
Inc.
Beatrice Lee/Bruce Santo
1655 Scott Blvd.
Santa Clara, CA 95050
Telephone: 408-985-2400

Vincotte USA, Inc.
Carl M. King
10497 Town & Country Way,
Suite 900
Houston, TX 77024
Telephone: 713-465-2850

* - Accredited by the RAB

APPENDIX B - CASE STUDY OF A SUCCESSFUL ISO 9000
CERTIFICATION

"Planning a Successful ISO 9000 Assessment," by George Dzus,
Quality Progress, V24(11), November 1991, 43-46.

In November of 1990, after a year of rigorous preparation the Du Pont Imaging Systems Plant in Towanda, PA, completed a successful assessment by representatives of the BSI and UL under the guidelines of ISO 9002. The Du Pont Imaging Plant has approximately 770 employees, manufactures photopolymer films, coated and laminated flexible composites, X-ray intensifying screens, photosensitive film and dielectric tape.

This plant became interested in ISO 9000 certification after a Du Pont plant in Neu-Isenberg Germany achieve registration to ISO 9000 in 1988 through the German Association for the Certification of Quality Systems. By the end of that year the European customers of the Tonawada plant were making inquiries concerning the registration status of that plant. A small group of quality professionals met with business managers to gain commitment and support for the assessment preparations. Many of the business managers indicated their beliefs that they thought only sites in Europe needed ISO 9000 certifications despite

the fact that the Towanda plant was exporting to Europe. The initial resistance faded as several of the registered European Du Pont sites began reporting benefits such as increased manufacturing yields and a decrease in customer complaints. Since official U.S. registration organizations were slow in emerging, Du Pont contacted the BSI for registration.

Preparation for assessment

In figure A.1 is an outline of the steps taken by the plant to registration. This effort required about one year of concerted effort to prepare for the ISO 9000 assessment. The company did not start from ground zero. Several of their product lines were already expected to meet the requirements of MIL-Q-9858A. Several customers conducted audits based on MIL-Q-9858A and MIL-I-45208A. The management of the plant had developed two detailed quality manuals (over 500 pages each), had documented work instructions, calibration systems, training programs, etc., already in place. During the preliminary overview it was discovered that most of these systems were not adequately defined, documented or religiously followed. It was also realized that none of the previous customer audits had been conducted with the same degree of competence and thoroughness as the ISO 9000 assessment would require.

They began their preparation by sending five people to

20 Steps to Registration

1. Obtain management commitment and began training for leaders and coordinators (November 1989).
2. Set up a steering team and sub teams to identify what needed to be done.
3. Began internal quality audit.
4. Held a two-day in-house seminar.
5. Compiled a quality manual.
6. Conduct ongoing quality audits and implemented corrective actions.
7. Filled out application for assessment and paid application fee.
8. Submitted the quality manual to BSI for assessment (March 1990).
9. The pre-assessment was conducted (April 1990).
10. Implemented improvements based on pre-assessment recommendations.
11. Set the date for being ready for assessment.
12. Set the assessment date for two to three months later.
13. Provided more in-house training.
14. Conducted frequent checks on status with plant leaders.
15. Got plant leaders to conduct audits.
16. Shared pre-assessment findings.
17. Sent revised quality manual to BSI.
18. The assessment was conducted (November 1991).
19. Fixed minor discrepancies.
20. Registration obtained (January 1991).

Figure A.1. Du Pont's Towanda Plant's 20 Steps to Registration.

seminars on ISO 9000 and auditing techniques. Organized a steering committee called the quality standard team, a procedure writing team, a training team, and two task teams to prepare the quality manual and to develop the internal quality auditing program. The management started immediately on conducting internal quality audits in 22 areas of the plant and continually redefined the auditing process as experienced was gained.

It was during this period the management brought in outside quality consultants who presented an in-house, two-day seminar on ISO 9000 for members of the quality standard teams and procedure-writing and training team. The purpose of this was to ensure that the people leading the implementation had a thorough knowledge on the standard and the assessment process.

The quality manual that was developed was based on BSI's recommendations and quality manuals from several of the European Du Pont sites. The existing manuals were abandoned. Specific information on the quality system operation, was documented in a series of core procedures called quality management procedures. Figure A.2 shows the hierarchy of the quality system documentation that was developed.

Prior to the pre-assessment, a copy of the quality manual was submitted to the BSI for evaluation. A written

Quality System Documentation Hierarchy

First Tier: Quality Manual

Second Tier: Quality management procedures (core procedures)

Third Tier: Area work instructions (standard operating procedures, test methods, etc.)

Fourth Tier: Forms, records, books, and files

Figure A.2. Quality System Documentation Hierarchy.

assessment was provided after the pre-assessment. The pre-assessment is an optional step but it was found to be a particularly valuable experience. One auditor conducted the pre-assessment in two days. The process is identical to the assessment but it is limited in time and scope. This process provides a preview of what the assessment will be like and should be considered a consulting visit.

A pre-assessment early in the preparation stage will allow enough time for mid-course adjustments and a better estimate of the company's readiness for assessment. Pre-assessment also gives the auditor an idea of the time frame that will be required. The pre-assessment might conclude with a statement such as "Had this been an actual assessment it would not have been possible to recommend registration." It is important to prepare the organization for this likely outcome so that the pre-assessment can be used as a spring board for improvement not a blow to employee's morale.

It is best to have a tough auditor for the pre-assessment. For example, the Du Pont's pre-assessment auditor found a discrepancy concerning volumetric glassware not being included in the calibration system. The auditor was not impressed with the explanation that it required the use of Class A volumetric glassware and suggested that the plant had no way of knowing the accuracy of our burets, pipettes, or flask. The plant did not know the age of the glassware

or what effects the chemicals that were used (especially alkaline solutions) had on measurement accuracy.

As a result, the plant management decided to mark all our volumetric glassware when it is put into service and, based on the chemical used, set up recalibration date. The Du Pont then chose two glassware suppliers and performed external quality audits. In retrospect, the management was grateful to the auditor for raising the issue because they gained better appreciation of glassware manufacturing, glassware specifications, and calibration schemes. It was of interest to note how the outgoing quality of a product could be related to an analytical balance as at a supplier's facility.

After the pre-assessment, the plant began implementing the auditor's suggested improvements. Du Pont quality consultants provided another two-day ISO 9000 seminar plus a two-hour overview seminar. The progress of the implementation of the improvements was frequently reviewed with plant leaders, who were also required to participate in internal quality audits.

Du Pont found that by sharing information about the pre-assessment and assessment discrepancies was extremely helpful. Discrepancies found in one Du Pont plant were often present in other sites. For example, one site reported that the auditor found a bottle of pH buffer

solution in use was beyond the expiration date on the label. The Towanda Plant checked their own supply of pH buffers and certified titration solutions, discarded expired solutions, and developed a system to check the chemical labels during routine internal audits.

Assessment structure

BSI considered the plant size as well as the pre-assessment report when it scheduled the assessment. BSI decided to use two auditors and one auditor-in-training (observer).

The assessment began with a brief introductory meeting attended by the auditors, plant leaders and the ISO area coordinators. It include introductions and a brief statement of how the assessment would be conducted. The meeting was followed by a one-hour plant tour to familiarize the auditors with the plant layout and operation.

After that the auditors held a brief private planning meeting. Then they broke up and began the audit. The lead assessor and the trainee began visiting and auditing various support functions, such as purchasing, customer service, warehousing, receiving, the quality assurance laboratory, and internal quality auditing. The second auditor focused on production areas, such as batch preparation, coating, slitting and packaging.

The assessment method

The auditor gains understanding of what specific areas or departments do by asking questions and reviewing procedures. The system for documentation control are usually checked in each area. It is important to note that the auditors considered that document control extends to notes, memos, labels, etc., especially those posted on a bulletin board or attached to equipment. For example, if there is a posted sign on a piece of production equipment saying "Always open valve before increasing steam pressure," it should be treated as a controlled document. Upon seeing such a sign, auditors may ask, "What if the equipment is modified and the procedure is updated?" or "Who is responsible for changing the sign?" The auditors also ask frequently such questions as "Where do you get your work instructions?" and "How do you know what to make when you first come to work each day?" The area procedures are expected to address these questions. This type of detail is often taken for granted and not included in written procedures.

The auditors typically take samples or follow an audit trail. This involves randomly selecting a material, instrument, or quality record and follow it through the system. For example, if records indicate the company received chemical X yesterday, the auditor will ask "Where is it now? Is it where it should be? Is the release status

recorded (e.g. awaiting test results or release for use)?" The auditor might select raw material from the approved supplier list and ask to see the purchasing documents for the last order. The auditor might select a sample that arrived in the lab that morning and ask to see the completed quality record (test results). Looking at a particular sample might lead an auditor to other departments to follow up on questions such as "What was done with this material next?" and "How was the material received and released when it first arrived?"

Murphy's law of auditing

Auditors almost always find the oddball in the quality system. This usually results in astonishment and comments such as "I can't believe you picked that one! That's the only raw material that we don't test here in our lab" or "I can't believe you picked the first lot in three years to have a customer complaint!" Numerous of these types of items surfaced during the internal quality audits.

Information collect by Du Pont over the period of evaluation suggest each auditor typically finds between four to 10 discrepancies per day. During the four-day assessment, two auditors documented a total of 31 discrepancies (about four per day per auditor). Although auditors look for evidence of a breakdown in the quality system and not the number of discrepancies, an accumulation

of minor discrepancies can be considered a breakdown or major discrepancy. Figure A.3 contains examples of types of discrepancies found at the Du Pont, Towanda Plant.

To ensure that a company hasn't crammed to pass the examination. BSI will have unannounced surveillance visits. It is expected that these visits will monitor ongoing improvement efforts of the plant's QMS and that the auditors' expectations will get increasingly higher.

The ISO 900 assessment was the most detailed and thorough audit of the plant the management had ever experienced. The auditors were highly professional, experienced and knowledgeable, thorough, and reasonable. The experienced taught the Du Pont Plant management was that just understanding the requirements and having systems that you believe meet ISO 900 requirements is not good enough. You need to understand what the auditors look for and how they interpret the standard.

The benefits

Although some of the benefits of ISO 9000 registration are immediately noticeable, some aren't. For example, the Du Pont Towanda plant, has had a reduction in process deviations. This reduction in variability was believed to be due to increased consistency in the way the production processes operated, especially from shift to shift. The increased consistency comes from the discipline required by

Examples of Discrepancies

1. Revision status of material specifications not described on purchase order (ISO 9002 Clause 4.5.3b).
2. Uncontrolled copies of procedure found to be in use (ISO 9002 Clause 4.4.1).
3. Data Base for limits in computer system does not agree with material specification 220002 (ISO 9002 Clause 4.4.1).
4. No certificate of calibration was available for viscosity tube B49.
5. Contract between Du Pont and Generic Trading Company does not show requirement for supplier to advise Du Pont prior to making changes to specifications as required by Du Pont Raw Material acceptance procedures (ISO 9002 Clause 4.5.3). Records of visits to and from the Generic Trading Company do not adequately demonstrate effective operation system (ISO 9002 Clause 4.15 and 4.5.2).

Figure A.3. Examples of Du Pont's Towanda Plant's Discrepancies.

ISO 9000.

Every company, whether it manufactures a product or provides a service should be concerned about meeting the ISO 9000 requirements. They provide a foundation for an effective quality system. When a company is registered, its customers are less likely to conduct their own assessment, saving time and money for both customers and suppliers. ISO 9000 registration makes companies more competitive.

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